IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG and TAKEDA PHARMACEUTICALS AMERICA, INC.,	)	C.A. No. 18-88 (LPS) CONSOLIDATED
Plaintiffs,	)	
v.	)	
LUPIN LIMITED, et al.,	)	
Defendants.	)	

LETTER TO THE HONORABLE LEONARD P. STARK REGARDING RESPONSE TO DEFENDANTS' AUGUST 12, 2021 LETTER

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Dear Judge Stark:

Plaintiffs submit this letter in response to the letter Defendants submitted on August 12, concerning *GlaxoSmithKline LLC v. Teva Pharms. USA*, No. 18-1976, _ F.3d _ (Fed. Cir. 2021) ("*GSK II*"). D.I. 1072. The Federal Circuit's opinion in *GSK II* provides additional support for finding induced infringement of U.S. Patent No. 9,278,096 in this matter.

GSK II confirms that an ANDA filer may induce infringement when its section viii carve out fails to fully remove an infringing use from the generic label. *GSK II* at 14–18; D.I. 1012 at 72–73; D.I. 1054 at 32–34; *see also AstraZeneca Pharm. LP v. Apotex, Corp.*, 669 F.3d 1042 (Fed. Cir. 2010). The touchstone of the induced infringement analysis in Hatch-Waxman cases such as this has been, and continues to be, whether the proposed generic labeling, considered as a whole, encourages, recommends, or promotes an infringing use. D.I. 1012 at 72–73, 81; D.I. 1047 at 79; D.I. 1054 at 32–34; *see also GSK II* at 25 ("Our precedent has consistently held that, when a product is sold with an infringing label or an infringing instruction manual, such a label is evidence of intent to induce infringement."). The Federal Circuit expressly rejected Teva's argument that its partial label did not induce because it "may encourage both infringing and noninfringing uses." *GSK II* at 17.

Notably, here, the indication for Defendants' products remains the *same* as Plaintiffs' Trintellix product. D.I. 1012 at 68, 81. And Plaintiffs' experts explained in detail how Defendants' prescribing information will encourage physicians to prescribe generic vortioxetine for the claimed method of treatment. D.I. 1012 at 73–83; D.I. 1054 at 32–49; *see GSK II* at 13–19 (detailing GSK's expert testimony comparing the claim to relevant sections of Teva's partial label). Such evidence that a label encourages an infringing use was relied on in *GSK II* and has been sufficient to establish induced infringement in case after case, including where Defendants have yet to sell or market their ANDA product. *See* D.I. 1012 at 73–83 (citing pre-launch Hatch-Waxman cases); D.I. 1054 at 32–49 (same). Furthermore, here, it is undisputed that physicians will read Defendants' prescribing information. *See, e.g.*, D.I. 1012 at 76. It is likewise undisputed that Defendants represent that their ANDA products are therapeutically equivalent to Trintellix®. *See, e.g.*, D.I. 1012 at 69; *see also GSK II* at 27–28 (evidence that Teva knew doctors would read its label and Teva's marketing of its product as a "therapeutic equivalent" of the brand supported the jury's finding of induced infringement).

Based on the record evidence in this case, a finding that Defendants will induce infringement of the '096 Patent if approved, is consistent with *GSK II* and Federal Circuit precedent regarding inducement in pre-launch Hatch-Waxman cases.

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/rs
cc: Clerk of the Court (via CM/ECF)
All Counsel of Record (via CM/ECF and email)